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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,557	04/01/2004	Ronald M. Jones	52325-8019.US00	1236

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,557	JONES, RONALD M.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/21/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and incomplete since the structural relationship between the sample distribution array and both the HDL test pad and reagent pad is not clear. Where in the device is the sample distribution array arranged relative to the HDL test pad and reagent pad?

Claim 6 is indefinite since it is not clear where in the device the sieving pad is located in relation to the sample distribution array, HDL test pad and reagent pad.

In claim 7, the phrase "said sieving pad" lacks antecedent basis since claim 7 depends from claim 1.

Lines 3-4 of claim 15 are indefinite since it is not clear whether both the reagent pad and HDL pad are formed of an asymmetric polysulfone membrane or whether only one of the reagent pad or HDL test pad are formed of an asymmetric polysulfone membrane.

On line 4 of claim 17, the phrase "said HDL test pad" lacks antecedent basis.

In claim 24, the phrases "said sieving pad" and "said sample distribution pad" lack antecedent basis.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 5-14 and 23-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al (US 2003/0224471).

Jones et al teach of a high density lipoprotein (HDL) assay device and method for measuring the concentration of HDL-associated cholesterol in a blood fluid sample. The device comprises a main body or support 15, which defines a well 16 sized to receive a quantity of blood. The well is in contact with a sieving pad 22 that is carried in a notched region 20 formed in the upper edge of the support. A capillary conduit 18 may connect the well 16 to the sieving pad 22. Sieving pad 22 functions to partially remove large particulate matter such as blood cells as the sample migrates through the pad matrix in a bottom-to-top direction. The sieving pad 22 in turn contacts an elongate strip or sample distribution matrix 26, which extends along the upper edge of the plate 15. Matrix 26 serves to distribute the sample from a central application region 28, which is in contact with the pad 22, to sample collection regions 30, 32 within the matrix. The device also includes a reaction bar 60 composed of an elongate support 62, and multiple wettable absorbent reaction test pads 64, 66, 68 and 70 carried on the lower surface of the support. Each test pad contains analyte-dependent reagents effective to produce an analyte-dependent change in the pad. One of the test pads is an HDL test pad 64 that contains reagents that react with HDL so as to detect the HDL. The HDL can be detected optically, or the HDL test pad can be a biosensor that electrochemically measures the production of oxygen or hydrogen peroxide. See paragraph nos. 0068-0069 in Jones et al. Some or all of the test pads are asymmetric membranes having a porosity gradient across the thickness of the membrane. The reaction bar is mounted on a support 15 by mounting means effective to maintain the device in either a sample-distribution position where the test pads and a reagent pad are spaced apart from

the sample distribution matrix or a test position, where the test pads and reagent pad are in fluid communication with the sample distribution matrix. The mounting means can be used to break fluid communication between the sample distribution matrix and the test pads after a desired amount of sample has entered the pads or after a predetermined contact time. The mounting means can include a pair of resilient members such as elastomeric blocks 71, 72. Upstream of the HDL test pad is a reagent pad 74 having immobilized therein a polyanionic reagent effective to bind and remove from the fluid sample non-HDL lipoproteins. The reagent pad 74 is located between the sample distribution matrix and the HDL test pad. The reagent pad 74 can be attached to the HDL test pad, as depicted in Figure 1. See paragraph nos. 0048-0059 in Jones et al. The polyanionic reagent in the reagent pad selectively removes LDL and VLDL particles from the fluid sample, and is preferably a sulfonated polysaccharide. The reagent pad 74 effectively traps non-HDL lipoproteins within the pad and prevents them from entering the HDL pad 64. In one embodiment, the reagent pad 74 consists of a single membrane, but in other embodiments, multiple stacked membranes may be used. The HDL test pad can be formed from a polysulfone membrane impregnated with reagents that detect HDL. The HDL test pad 64 can also be laminated to the reagent pad 74 before the application of reagents, and the respective reagents are then applied, first to one side of the laminate and then to the other. See paragraph nos. 0088-0089 in Jones et al.

4. Claims 1, 5-14 and 23-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al (US 2003/0166291).

Jones et al teach of a high density lipoprotein (HDL) assay device and method for measuring the concentration of HDL-associated cholesterol in a blood fluid sample. The device

comprises a main body or support 15, which defines a well 16 sized to receive a quantity of blood. The well is in contact with a sieving pad 22 that is carried in a notched region 20 formed in the upper edge of the support. A capillary conduit 18 may connect the well 16 to the sieving pad 22. Sieving pad 22 functions to partially remove large particulate matter such as blood cells as the sample migrates through the pad matrix in a bottom-to-top direction. The sieving pad 22 in turn contacts an elongate strip or sample distribution matrix 26, which extends along the upper edge of the plate 15. Matrix 26 serves to distribute the sample from a central application region 28, which is in contact with the pad 22, to sample collection regions 30, 32 within the matrix. The device also includes a reaction bar 60 composed of an elongate support 62, and multiple wettable absorbent reaction test pads 64, 66, 68 and 70 carried on the lower surface of the support. Each test pad contains analyte-dependent reagents effective to produce an analyte-dependent change in the pad. One of the test pads is an HDL test pad 64 that contains reagents that react with HDL so as to detect the HDL. The HDL can be detected optically, or the HDL test pad can be a biosensor that electrochemically measures the production of oxygen or hydrogen peroxide. See paragraph nos. 0072-0076 in Jones et al. Some or all of the test pads are asymmetric membranes having a porosity gradient across the thickness of the membrane. The reaction bar is mounted on a support 15 by mounting means effective to maintain the device in either a sample-distribution position where the test pads and a reagent pad are spaced apart from the sample distribution matrix or a test position, where the test pads and reagent pad are in fluid communication with the sample distribution matrix. The mounting means can be used to break fluid communication between the sample distribution matrix and the test pads after a desired amount of sample has entered the pads or after a predetermined contact time. The mounting

means can include a pair of resilient members such as elastomeric blocks 71, 72. Upstream of the HDL test pad is a reagent pad 74 having immobilized therein a polyanionic reagent effective to bind and remove from the fluid sample non-HDL lipoproteins. The reagent pad 74 is located between the sample distribution matrix and the HDL test pad. The reagent pad 74 can be attached to the HDL test pad in permanent contact, as depicted in Figure 1. See paragraph nos. 0050-0065 in Jones et al. The polyanionic reagent in the reagent pad selectively removes LDL and VLDL particles from the fluid sample, and is preferably a sulfonated polysaccharide. The reagent pad 74 effectively traps non-HDL lipoproteins within the pad and prevents them from entering the HDL pad 64. The asymmetric membrane of the reagent pad 74 is preferably oriented with its larger pored surface facing the sample distribution matrix 26, and its smaller pored surface facing and contacting the HDL test pad 64. This orientation allows free access of sample into the reagent pad through the larger pores, and prevents passage of precipitated material, formed as the sample contacts the precipitating agent in the reagent pad, through the smaller pores. See paragraph no. 0066 in Jones et al. In addition, the asymmetric membrane employed as the HDL test pad is oriented with its smaller pored surface facing upward and its larger pored surface facing reagent pad 74. See paragraph no. 0068 in Jones et al. In one embodiment, the reagent pad 74 consists of a single membrane, but in other embodiments, multiple stacked membranes may be used. See paragraph no. 0067 in Jones et al. The HDL test pad can be formed from a polysulfone membrane impregnated with reagents that detect HDL. The HDL test pad 64 can also be laminated to the reagent pad 74 after the application of reagents. See Figure 3 and claim 19 in Jones et al.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-4 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al (US 2003/0166291) in view of both Kitani et al and Ditter et al. For a teaching of Jones et al, see previous paragraphs in this Office action. Jones et al fail to teach laminating the HDL test pad and reagent pad to one another by the use of a heat formed bond and an acrylic acid copolymer adhesive.

Kitani et al teach of a dry analysis element used for the quantitative analysis of an analyte in a whole blood sample. The device comprises multiple layers such as a support, a reagent layer, a porous layer, a volume filtering layer, and a detection layer all laminated together. Kitani et al teach that the layers in the analytical device can be laminated together through the use of a heat-responsive adhesive applied at the interface between two adjacent layers. The adhesive is coated onto the layers discontinuously on the interface between two layers so as not to hinder the uniform passage of a liquid through and between the two adjacent layers. Examples of the adhesives used by Kitani et al include hot-melt type adhesives such as ethylene acrylic acid copolymer. See lines 18-39 in column 11 and lines 5-27 in column 12 of Kitani et al.

Ditter et al also teach of laminated asymmetric membranes used as filters. The asymmetric membranes including pores therein are laminated together by the use of a hot melt adhesive. One of the hot melt adhesives used includes polyethylenevinylacetate. Ditter et al

teach that the membranes are laminated together by the application of a hot melt adhesive between the layers, and heating to a temperature that is higher than a melting point of the adhesive and lower than a melting point of the asymmetric membranes. The heating is usually performed at about 200°F or less. See lines 42-51 in column 2 and lines 21-33 in column 3 of Ditter et al.

Based upon the combination of Jones et al with both Kitani et al and Ditter et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to laminate the HDL test pad and the reagent pad taught by Jones et al to one another by the use of a heat formed bond and an acrylic acid copolymer adhesive since Jones et al teach to laminate the HDL test pad and reagent pad together, and both Kitani et al and Ditter et al teach that a common way in which to laminate together asymmetric membranes used in analytical test devices is by the application of a heat sensitive adhesive material such as ethylene acrylic acid copolymer to the membranes, placing the membranes over one another and heating so as to adhere the membranes to one another.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Hewett who teaches of a device for determining the concentration of an analyte in a body fluid sample that has a structure similar to the device recited in the instant claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 10, 2005

Maureen M. Wallenhorst
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